IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-731 (***)
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION TO STRIKE

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals Co. ("Penwest") (collectively, "Plaintiffs") hereby oppose defendant Impax Laboratories, Inc.'s ("Impax") Motion to Strike on the grounds set forth below.

INTRODUCTION

This is an action filed pursuant to the so-called "Hatch-Waxman Act" provisions of the Federal Food, Drug, & Cosmetic Act. The Hatch-Waxman Act provides an orderly process for litigating patent disputes relating to Abbreviated New Drug Applications ("ANDAs"), which generic manufacturers file when seeking approval from the United States Food and Drug Administration ("FDA") to bring a generic drug to market. This case, however, is highly unusual.

Here, Impax jumped the gun, prematurely triggering the ANDA litigation process at a time when it had no ANDA that the FDA had accepted for substantive review. Plaintiffs asked Impax not to pursue that process until it had a proper ANDA on file, but Impax declined. As a result, in order to preserve their statutory rights under the Hatch-Waxman scheme, Plaintiffs had no practical choice but to institute this action. Plaintiffs' infringement claims, however, are

explicitly asserted in the alternative—*i.e.*, solely in the event that Impax's actions were deemed proper.

As Plaintiffs explained in their Complaint, although Impax's improper actions forced them to file infringement claims to preserve their statutory rights, they should not be forced to pursue those rights in this action. Instead, such claims should proceed only after Impax has submitted a proper ANDA that the FDA accepted for substantive review. At that point, Impax would be able to serve a proper notice on Plaintiffs, thereby triggering the ANDA litigation process, and Plaintiffs could pursue their infringement claims in an action filed in response.[1]

For these reasons, the procedural and regulatory context explained in Plaintiffs' Complaint is critical to understanding the nature of Plaintiffs' claims in this case. But it is exactly that context which Impax seeks to have stricken.

Impax cannot meet the high standard required to justify the drastic measure of striking pleadings that purportedly are "immaterial" or "impertinent" under Rule 12(f). To the contrary, the allegations that Impax seeks to strike are highly material to this matter for a variety of reasons. Among other things, those allegations provide the necessary background and context for Plaintiffs' patent infringement claims, which are pled in the alternative; they form part of the basis for plaintiffs' claim that this is an exceptional case, deserving an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and they are relevant to the affirmative defenses that

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[1] Indeed, as is set forth below, after Plaintiffs filed their Complaint, Impax submitted an amended ANDA which the FDA apparently has accepted for substantive review, and Impax thereafter served notices properly triggering the ANDA litigation process, which Plaintiffs received on December 14, 2007. Plaintiffs intend to file a new Complaint asserting patent infringement claims against Impax based on those facts within the 45-day period for doing so provided under the Hatch-Waxman Act. Plaintiffs' patent infringement claims against Impax should proceed in that action, not this one.

Plaintiffs assert in reply to Impax's counterclaims. Moreover, Impax has not even alleged, let alone affirmatively demonstrated, that it will suffer any prejudice if the allegations at issue are not stricken.

Impax's motion is simply a procedural maneuver to permit it to seek to avoid having to answer for its improper conduct. That is not a proper basis for a motion to strike. The Court should deny Impax's motion.

FACTUAL AND PROCEDURAL BACKGROUND

A. Overview Of The ANDA Litigation Process

A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and the FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"). *See* 21 U.S.C. § 355(b)(1) and (c)(2).

On the other hand, a company seeking to market a generic version of an already approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and the FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug.

As part of the generic approval process, an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the innovator drug at issue. *See* 21 U.S.C. § 355(j)(2)(A)(vii). An ANDA filer may certify, for example, that it

believes a listed patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This is known as a so-called "Paragraph IV Certification."

The sponsor of an ANDA with a Paragraph IV Certification must also provide notice to both the owner of the listed patent and the sponsor of the NDA for the listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent in invalid or not infringed by the proposed generic product. 21 C.F.R. § 314.95(c). A properly served Paragraph IV Notice triggers the ANDA litigation process, intended to give parties an opportunity to resolve patent disputes before generic approval.

If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice, final approval of the ANDA is generally subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The first ANDA applicant to submit and lawfully maintain a Paragraph IV Certification with respect to an approved drug may be entitled to 180 days of marketing exclusivity, during which time no other ANDA filer may come to market with a competing generic product. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

Timing is crucial in applying the 30-month stay and determining eligibility for the 180-day exclusivity period. The 30-month stay, for example, applies if the innovator company files an infringement action within 45 days of receiving a Paragraph IV Notice, if the relevant patent was submitted for listing in the Orange Book before the ANDA applicant had submitted a substantially complete ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Likewise, a generic manufacturer is entitled to the 180-day market exclusivity period only if it is deemed to be a "first applicant," as determined based on the date that it has submitted "a substantially complete

application that contains and lawfully maintains a [Paragraph IV Certification] for the drug." *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

A generic applicant thus has powerful incentives to obtain the earliest filing date possible for its ANDA, even if that requires filing a "sham" or incomplete ANDA. Congress and the FDA recognized this risk. As a result, a generic applicant may not trigger the ANDA litigation process until the FDA has accepted its ANDA for substantive review. *See* 21 C.F.R. § 314.95(b). Here, however, Impax improperly jumped the gun.

B. Impax's Improper Attempt To Trigger The ANDA Litigation Process

On June 1, 2006, the FDA approved Endo's new drug application No. 21-610 for OPANA® ER tablets, for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. *See* Complaint, ¶ 21.

On October 2, 2007, the U.S. Patent & Trademark Office ("PTO") issued United States Patent No. 7,276,250 ("the '250 patent"), to Penwest as assignee. *See id.*, ¶ 24. That same day, Endo submitted information regarding the '250 patent to the FDA for listing in the Orange Book with respect to OPANA® ER tablets. *Id.*, ¶ 25. Also on that same day, Impax sent Endo and Penwest a Paragraph IV Notice stating that it had submitted ANDA No. 79-087 seeking approval to manufacture, use, or sell a generic version of OPANA® ER prior to the expiration of the '250 patent. *Id.*, ¶ 29.

Just two days later, however, on October 4, 2007, Impax issued a press release in which it admitted that the FDA had ***"rescinded its initial acceptance"*** of Impax's ANDA and that Impax was "working with the FDA to correct any deficiencies of the ANDA." *Id.*, ¶ 35. Despite Impax's public acknowledgement that the FDA had not accepted its ANDA for filing, it continued to inundate Endo and Penwest with additional Paragraph IV Notices. On October 3, 4, 5 and 9, Impax sent Endo and Penwest four additional, substantively identical notices. *Id.*, ¶ 38.

Endo and Penwest demanded that Impax withdraw its Paragraph IV Notices, but Impax declined. *Id.*, ¶ 46. Instead, Impax continued to act as if the FDA actually had accepted its ANDA for review. On October 19, 2007, for example, Endo submitted information regarding two additional patents – United States Patent Nos. 5,662,933 ("the '933 patent") and 5,958,456 ("the '456 patent") – to the FDA for listing in the Orange Book with respect to OPANA® ER tablets. Again, despite Impax's public acknowledgement that the FDA had rescinded acceptance of its ANDA, Impax served yet another Paragraph IV Notice on Endo and Penwest, this time with respect to the '933 and '456 patents. *Id.*, ¶ 41.

Impax had no right to trigger and continue to pursue the ANDA litigation process at that time, because the FDA had rescinded acceptance of Impax's ANDA. Plaintiffs again demanded that Impax withdraw the Notices, but Impax has continued to refuse to do so. Moreover, Impax has also refused to provide Plaintiffs with even the most basic information regarding FDA's rescission of its ANDA, including the date on which Impax first learned that FDA rescinded its initial acceptance or the basis for FDA's rescission. *Id.*, ¶ 46.

C. Plaintiffs' Commencement Of This Action And Subsequent Events

As a result, Plaintiffs had no practical choice but to institute this action within 45 days of receiving the first of Impax's improper Paragraph IV Notices, in order to preserve their statutory rights under the Hatch-Waxman Act. Accordingly, in their Complaint, Plaintiffs asserted a declaratory judgment claim (Count I), seeking a declaration that Impax's attempt to trigger the ANDA litigation process was premature, improper and contrary to law. Plaintiffs also asserted, in the alternative, claims for infringement of the '933 and '456 patents. Pursuant to Rule 57, Plaintiffs promptly moved for expedited declaratory judgment relief, seeking an order declaring, *inter alia*, that Impax's Paragraph IV Notices did not commence the 45-day period for filing a patent infringement action; declaring that if and when the FDA accepts Impax's ANDA,

Impax must submit and serve on Plaintiffs new patent certifications at that time; and ultimately, dismissing its patent infringement claims as moot.

Thereafter, Impax amended its ANDA. By letter dated December 13, 2007, Impax advised Plaintiffs that the FDA deemed Impax's amended ANDA acceptable for filing as of November 23, 2007, and included with that letter a new Paragraph IV Notice. *See* Ex. 1. To the best of plaintiffs' knowledge, this new Paragraph IV Notice properly triggered the ANDA litigation process. Based on this new development, Plaintiffs voluntarily dismissed their declaratory judgment claim (Count I of their Complaint) and withdrew their motion for expedited declaratory judgment relief. In their Notice of Dismissal (Ex. 2), however, Plaintiffs made clear that it remains their position that Impax's prior Paragraph IV Notices (*i.e.*, those that Plaintiffs received prior to December 14, 2007) are null, void and without legal effect. Plaintiffs nevertheless did not dismiss Counts II and III of the Complaint for patent infringement based on Impax's pre-December 14 Notices because Impax continues to refuse to withdraw those Notices and takes the position that they are valid.

As Plaintiffs further explained in their Notice of Dismissal, they intend to file a claim for infringement based on Impax's most recent Paragraph IV Notice, the one that it appears was properly served, within the 45-day period prescribed by the Hatch-Waxman Act. That action, rather than this one, is the one in which Plaintiffs' patent infringement claims should properly proceed.

ARGUMENT

Rule 12(f) motions are strongly disfavored, as they represent "a drastic remedy to be resorted to only when required for the interests of justice.'" *Poole v. Taylor*, 466 F.Supp.2d 578, 583 (D. Del. 2006). *See also* 5C Charles Alan Wright & Arthur R. Miller, Federal Practice

& Procedure, § 1380 (Civ. 3d ed. 2007) ("Both because striking a portion of a pleading is a drastic remedy and because it often is sought by the movant simply as a dilatory or harassing tactic, numerous judicial decisions make it clear that motions under Rule 12(f) are viewed with disfavor by the federal courts and are infrequently granted."); *Rechsteiner v. Madison Fund, Inc.*, 75 F.R.D. 499, 505 (D. Del. 1977). In considering a motion to strike, the burden lies with the movant and the court will draw all reasonable inferences in the pleader's favor and resolve all doubts in favor of denying the motion to strike. *Nwachukwu v. Karl*, 216 F.R.D. 176, 178 (D. D.C. 2003).

Accordingly, it is well-settled in this Court that to succeed on a motion to strike, the movant must demonstrate both (i) that the allegations it seeks to strike "have no possible relation to the controversy," and (ii) that the movant will suffer prejudice if those allegations are not stricken. *See, e.g., Poole*, 466 F.Supp.2d at 583; *Rechsteiner*, 75 F.R.D. at 505. Impax's perfunctory motion completely ignores this heavy burden and fails to satisfy either prong of this governing standard.

A. Impax Does Not Claim Any Prejudice

Impax completely ignores the second prong of the standard governing motions to strike, and does not even argue that it will suffer any prejudice if Plaintiffs' allegations are not stricken. Indeed, although Impax would like to avoid being held responsible for its improper gamesmanship, there can be no prejudice to Impax merely from having to admit or deny the facts that Plaintiffs allege. This glaring deficiency, in and of itself, warrants denial of Impax's motion.

B. The Allegations Impax Seeks To Strike Are At The Heart Of The Present Proceedings

Far from having "no possible relation" to the present controversy (as Impax conclusorily asserts), the allegations that Impax seeks to strike are directly relevant to the present proceedings in at least several important ways.

First, those allegations provide the context for understanding Counts II and III. *See, e.g., Lundy v. Town of Brighton*, ___ F. Supp.2d __, 2007 WL 3312475, *5 (W.D.N.Y. 2007) (denying motion to strike where, although the allegations at issue were not independently actionable, court could not conclude that they had "no bearing" on the plaintiff's claims); *Geer v. Cox*, 242 F. Supp.2d 1009, 1026 (D. Kan. 2003) (denying motion to strike where allegations provided background and context for claims asserted in complaint). Plaintiffs' position remains that Impax Notices 1 – 6 (as defined in the Complaint, *see* Ex. 2 at ¶¶ 29, 38, 41) are improper, yet Impax continues in its refusal to withdraw those Notices (even after serving the December 14 Notice). Impax's refusal has forced Plaintiffs to maintain their patent infringement claims in this action "in the event that Impax's Paragraph IV Notices are deemed to be effective." (*See* Ex. 2 at ¶¶ 58, 63.) The allegations that Impax seeks to strike set forth the facts regarding Impax's improper service of its Notices and the circumstances that required Plaintiffs to assert their infringement claims, expressly in the alternative, in this action. They provide the factual background necessary to place Plaintiffs' infringement claims in the appropriate context.

In addition, the allegations that Impax seeks to strike are directly relevant to Endo's claim that this case is exceptional under 35 U.S.C. § 285. Impax served no less than six invalid Paragraph IV notices, when it knew that the FDA had not accepted its ANDA for review. In so doing, Impax sought to game the system and gain an unfair and unlawful advantage vis-à-vis Endo, Penwest and other generic manufacturers by prematurely triggering the ANDA

litigation process under the Hatch-Waxman Act. Impax's improper conduct forced Plaintiffs to incur significant time, effort and expense in pursuing extraordinary legal proceedings, including having to institute litigation prematurely and to seek expedited declaratory relief. Impax's improper conduct, and the unnecessary and unwarranted litigation proceedings engendered thereby, render this case exceptional and form a basis for Plaintiffs' claim for attorneys' fees under § 285. *See, e.g., Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551-52 (Fed. Cir. 1989); *Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000).

Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc., 2005 WL 3664014 (D.N.J. 2005), is particularly instructive on this point. There, Novartis included allegations in its complaint that Teva's paragraph IV notice was substantively deficient, and Teva moved to strike those allegations on the grounds that they were immaterial because Novartis could not assert a cognizable cause of action based on a deficient notice letter. The court rejected Teva's motion, finding that the allegations were relevant to Novartis' claim that the case was "exceptional" under § 285 and therefore should not be stricken. *Id.* at *2. The same is true here – Plaintiffs' allegations are directly relevant to their claim that this is an exceptional case.[2]

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[2] The principal case on which Impax relies, *Biovail Labs v. Torpharm, Inc.*, 2003 WL 21254417, *2 (N.D. Ill. 2003), is readily distinguishable for at least two reasons. First, the allegations in *Biovail* challenged the sufficiency of the content of a Paragraph IV Notice for purposes of determining infringement. Here, by contrast, the allegations do not relate to the substantive content of Impax's Notices, but rather, to whether or not the necessary predicate for serving them at all, and thereby triggering the ANDA litigation process, existed at the time. Thus, Plaintiffs' allegations in this case go directly to the alternative nature of their infringement claims and the question of whether this Court has jurisdiction over the claims in this action—issues not presented in *Biovail*. In addition, in *Biovail*, there apparently was no "exceptional" case claim to which the stricken allegations were relevant.

Moreover, the allegations Impax seeks to strike are also relevant to Plaintiffs' defenses to Impax's counterclaim seeking a declaration of non-infringement and invalidity of Plaintiffs' patents. Pursuant to 35 U.S.C. § 271(e)(5), ANDA applicants cannot assert such declaratory judgment claims until 45 days after serving a valid Paragraph IV Notice, or after it has been sued for patent infringement based on that Notice, whichever occurs first. Here, Impax filed its counterclaim on December 20, 2007, only six days after Impax's December 14 Notice (the only possibly proper Paragraph IV Notice) and before Plaintiffs sued Impax based on that Notice. Accordingly, Impax's counterclaim is invalid. The allegations Impax seeks to strike make clear that Impax's earlier Paragraph IV Notices were null and void, such that they cannot provide the predicate necessary to support Impax's counterclaim, and thus provide background and support for the affirmative defenses Plaintiffs assert in their Reply to Impax's Counterclaim (*see* Ex. 3).[3]

Fundamentally, Impax seeks via its motion to transform this action into something it is not – a straightforward, run-of-the-mill Hatch-Waxman Act infringement action. To the contrary, this is a highly unusual case in which Impax's gamesmanship has forced Plaintiffs to expend significant resources prematurely and unnecessarily on issues that should never have arisen. For purposes of the present motion, the Court must accept Plaintiffs' allegations as true and analyze Plaintiffs' Complaint and claims for what they are, not what Impax would like them to be.

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[3] A close examination of the particular allegations that Impax moves to strike also illustrates that its motion makes no sense. In several instances, Impax seeks to strike a phrase or even just a single word from a single sentence in one paragraph of the Complaint. *See* Impax Motion, ¶ 3. Impax also seeks to strike certain paragraphs (*e.g.*, 44-46), but not others (*e.g.*, 58 and 63), which only make sense in light of the allegations it does seek to strike. In any event, the purpose of a motion to strike is not to have the Court micromanage each word, sentence and paragraph in a pleading.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Impax's Motion to Strike in its entirety.

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January 14, 2008

CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Mary B. Mattterer
MORRIS JAMES LLP

I further certify that I caused to be served copies of the foregoing document on January 14, 2008 upon the following in the manner indicated:

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EXHIBIT 1

30831 Huntwood Avenue Hayward, CA 94544
Phone (510) 476-2000 Fax (510) 476-2092

December 13, 2007

Via Federal Express

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100 Endo Blvd.
Chadds Ford, PA 19317

Tracking # 8613 5929 5672

Penwest Pharmaceuticals Co.
39 Old Ridgebury Rd., Suite 11
Danbury, CT 06810

Tracking # 8613 5929 5683

Re: Paragraph IV Patent Certification Notice
U.S. Patent Nos. 5,662,933; 5,958,456; and 7,276,250

IMPAX Laboratories Inc.'s ANDA 79-087
Oxymorphone Hydrochloride Extended-Release Tablets
5 mg, 10 mg, 20 mg and 40 mg

To Whom It May Concern:

Please be advised that, in a letter dated December 12, 2007, the U.S. Food and Drug Administration ("FDA") has informed IMPAX Laboratories, Inc. ("IMPAX") that its ANDA 79-087 for Oxymorphone Hydrochloride Extended-Release Tablets 5 mg, 10 mg, 20 mg and 40 mg has been deemed acceptable for filing and substantive review by FDA as of November 23, 2007. FDA's letter also requests that IMPAX provide the notice and information required by 21 U.S.C. §§ 355(j)(2)(B)(i) and (ii) (§§ 505(j)(2)(B)(i) and (ii) of the Federal Food, Drug and Cosmetic Act).

Accordingly, as requested by FDA, we hereby notify you that IMPAX, a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544, has submitted an ANDA for the above-referenced drug product which contains the required bioavailability and/or bioequivalence data and Paragraph IV Certifications with respect to U.S. Patent Nos. 5,662,933; 5,958,456; and 7,276,250. Detailed statements of the

factual and legal bases for IMPAX's position regarding these patents are provided herein. IMPAX reserves the right to assert additional grounds, reasons and authorities for its position that the aforesaid patents are invalid, unenforceable, or not infringed.

By providing this notice, IMPAX does not intend to and does not waive any, and expressly reserves all, rights to challenge, either administratively or otherwise, FDA's unlawful rescission of the initial acceptance of IMPAX's ANDA. Accordingly, IMPAX does not and will not withdraw its prior Paragraph IV Notices, which were properly provided pursuant to the initial acceptance of IMPAX's ANDA, and which notices fully satisfy all statutory and regulatory requirements.

Please be further advised that, pursuant to 21 C.F.R. § 314.95(e), IMPAX requested and received from FDA permission to send this notice by means other than registered or certified mail. Specifically, IMPAX requested that it be allowed to send this notice by FedEx®. FDA granted IMPAX's request prior to this notice being sent.

Sincerely,
IMPAX Laboratories, Inc.

Michelle F. Wang for MCS

Mark C. Shaw
Vice-President, Regulatory Affairs
and Compliance

MCS/aks

Enclosures: IMPAX Laboratories, Inc.'s Detailed Statement of the Factual and Legal Bases That U.S. Patent Nos. 5,662,933 and 5,958,456 are Invalid, Unenforceable and/or Not Infringed

IMPAX Laboratories, Inc.'s Detailed Statement of the Factual and Legal Bases That U.S. Patent No. 7,276,250 is Invalid, Unenforceable and/or Not Infringed

cc: Jack B. Blumenfeld
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EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-731 (***)
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

NOTICE OF DISMISSAL OF COUNT I OF PLAINTIFFS' COMPLAINT AND WITHDRAWAL OF PLAINTIFFS' MOTION FOR EXPEDITED DECLARATORY JUDGMENT RELIEF

WHEREAS defendant Impax Laboratories, Inc. ("Impax") has represented to plaintiffs Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. (collectively, "Plaintiffs") that the United States Food and Drug Administration has deemed Impax's ANDA 79-087 acceptable for filing and substantive review as of November 23, 2007; and

WHEREAS Plaintiffs received, on December 14, 2007, a new Paragraph IV Notice from Impax with respect to United States Patent Nos. 5,662,933 and 5,958,456;

NOW, THEREFORE, PLEASE TAKE NOTICE THAT, pursuant to Fed. R. Civ. P. 41(a)(1), Plaintiffs hereby dismiss Count I of their Complaint, without prejudice. This dismissal is without waiver of or other prejudice to Plaintiffs' contentions that Impax's prior Paragraph IV Notices (*i.e.*, those that Plaintiffs received prior to December 14, 2007) are null, void and without legal effect. Plaintiffs are maintaining their claim for patent infringement based on Impax's pre-December 14, 2007 Paragraph IV Notices because Impax has refused to withdraw such Notices and continues to take the position that such Notices are valid. Plaintiffs will file a claim for infringement based on the December 14, 2007 Notice within the prescribed 45 day period.

PLEASE TAKE FURTHER NOTICE THAT Plaintiffs also withdraw, without prejudice, their Motion for Expedited Declaratory Judgment Relief (D.I. 6), filed on November 20, 2007, which sought expedited declaratory judgment relief pursuant to Count I of their Complaint.

MORRIS NICHOLS ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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Date: December 20, 2007

CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Mary B. Mattterer
MORRIS JAMES LLP

I further certify that I caused to be served copies of the foregoing document on December 20, 2007 upon the following in the manner indicated:

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/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-731 (***)
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

PLAINTIFFS' REPLY TO DEFENDANT'S COUNTERCLAIMS

Plaintiffs/counterclaim defendants Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals Co. ("Penwest") (collectively, "Plaintiffs"), for their reply to the Answer and Counterclaims filed by defendant/counterclaim plaintiff Impax Laboratories, Inc. ("Impax"), upon knowledge as to their own acts, and upon information and belief as to all other matters, hereby respond and allege as follows:

REPLY TO DEFENDANT'S COUNTERCLAIMS

71. Plaintiffs repeat and reallege their allegations with respect to paragraphs 1 to 46 and 57-66 of their Complaint as if set forth at length herein.

72. Denied as stated. Impax's Paragraph IV Notices 1 – 6 (as defined in Plaintiffs' Complaint) are null, void and without legal effect. Therefore, no actual case or controversy properly exists with respect to issues concerning the infringement and validity of United States Patent Nos. 5,662,933 ("the '933 patent") and 5,958,456 ("the '456 patent") based on those Notices. Impax, however, refused to withdraw Notices 1-6, and as a result, Plaintiffs were improperly forced to file this action to preserve their rights under the Hatch-Waxman Act. Impax subsequently served a Paragraph IV Notice on December 13, 2007 (*i.e.*, after the FDA deemed Impax's amended ANDA No. 79-087 acceptable for filing as of November 23, 2007).

However, pursuant to 35 U.S.C. § 271(e)(5), Impax is not entitled to assert any declaratory judgment counterclaims based on the December 13 Notice, because this action is based on Impax's Paragraph IV Notices 1 – 6 and because the 45-day period in which Plaintiffs may file suit based on the December 13 Notice has not yet run. By way of further answer, Plaintiffs deny that Impax's commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets would not infringe the '456 and '933 patents, deny that either the '456 or the'933 patent is invalid, and deny the remaining allegations and implications of this paragraph.

PARTIES

73. Admitted.

74. Admitted.

75. Admitted.

JURISDICTION AND VENUE

76. Denied as stated. Plaintiffs incorporate their reply to paragraph 72 as if fully set forth herein. Plaintiffs deny that Impax is entitled pursuant to 35 U.S.C. § 271(e)(5) to assert any declaratory judgment counterclaims at this time with respect to the infringement and validity of the '456 or the '933 patent, and deny therefore that this Court presently has jurisdiction over any such counterclaims. Plaintiffs further deny the remaining allegations and implications of this paragraph.

77. Admitted in-part and denied in-part. Plaintiffs admit that this Court has personal jurisdiction over them, and that venue would be proper in this Court for Impax's counterclaim if this Court had subject matter jurisdiction over it. Plaintiffs deny the remaining allegations and implications of this paragraph.

DEFENDANT'S COUNTERCLAIM

78. Plaintiffs repeat and reallege their allegations and responses with respect to paragraphs 1 to 46 and 57-66 of their Complaint and paragraphs 71-77 of this Reply as if set forth at length herein.

79. Denied as stated. Plaintiffs incorporate their reply to paragraphs 72 and 76 as if fully set forth herein. Plaintiffs further deny any contention that Impax's commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets would not infringe the '456 and '933 patents, deny that either the '456 or the '933 patent is invalid, and deny the remaining allegations and implications of this paragraph.

80. Admitted in-part and denied in-part. Plaintiffs admit that they filed the Complaint that commenced this suit on November 15, 2007, that as alleged therein, Penwest is the assignee and owner of the '456 and '933 patents, and that Endo is an exclusive licensee of these patents in the relevant field of use pursuant to a strategic alliance agreement with Penwest. Plaintiffs further admit that, as alleged in their Complaint, the '456 and '933 patents are listed in the Orange Book with respect to OPANA® ER tablets, which are the subject of NDA No. 21-610. Plaintiffs further admit that Impax requested that Plaintiffs provide it with a perpetual covenant not to sue for infringement of the'456 and '933 patents, and that they refused to do so. Plaintiffs further admit that they issued a joint press release on December 17, 2007, which press release speaks for itself. Plaintiffs deny the remaining allegations and implications of this paragraph.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

AFFIRMATIVE DEFENSES

1. Impax's counterclaim is premature and barred, in whole or in part, by 35 U.S.C. § 271(e)(5).

2. This Court presently lacks jurisdiction over any claim relating to issues concerning the infringement and validity of the '456 patent and the '933 patent.

3. Impax's counterclaim is barred, in whole or in part, because Impax purported to serve Impax Notices 1 – 6 (as defined in Plaintiffs' Complaint) pursuant to a valid ANDA at a time when Impax knew that it had no valid ANDA on file and accepted by FDA for substantive review.

4. Impax's counterclaim is barred, in whole or in part, because Impax Notices 1 – 6 (as defined in Plaintiffs' Complaint) are null, void and without legal effect, and none of those Notices commenced the 45-day period for filing a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

5. Impax's counterclaim is barred, in whole or in part, by the doctrines of unclean hands and/or equitable estoppel.

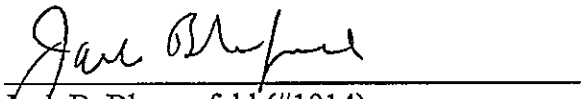
6. The Court should exercise its discretion to decline to hear Impax's counterclaim for declaratory judgment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray that the Court deny all of Impax's requested relief and find in favor of Plaintiffs on all Counts, dismiss Impax's Counterclaim with

prejudice, award Plaintiffs the relief they seek in their Complaint, and award Plaintiffs their costs and attorneys fees, as well as such other relief as the Court deems equitable and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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January 14, 2008

CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Mary B. Mattterer
MORRIS JAMES LLP

I further certify that I caused to be served copies of the foregoing document on January 14, 2008 upon the following in the manner indicated:

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